DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 18 1986

Re: Duromedics Cardiac
Valve Prosthesis
Docket No. 86E-0460

Charles E. Van Horn, Esq.
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent extension for U.S. Patent No. 4,328,592 filed by Hemex, Inc. under Title II of Public Law 98-417, 35 U.S.C. 156. The medical device claimed by the patent is the Duromedics Cardiac Valve Prosthesis, premarket application (PMA) number P850006.

A review of the Food and Drug Administration's official records indicates that the Duromedics Cardiac Valve Prosthesis, the product identified in the patent extension application, was subject to a regulatory review period before its commercial marketing or use as required by 35 U.S.C. 156(a)(4). Our records also indicate that PMA No. P850006 represents the first permitted commercial marketing or use of this product under section 515(d) of the Federal Food, Drug, and Cosmetic Act. FDA approved the Duromedics Cardiac Valve Prosthesis on August 29, 1986 which makes the submission of the patent term restoration application on October 24, 1986 timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent extension and a determination of the applicable regulatory review period is thus necessary, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Mr. James J. Schumann
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